

Serial No. 10/659,509 - Nachman et al.

REMARKS

Claims 1-19 remain of record in this application. Claim 1 has been amended and claims 20-40 have been cancelled. No new claims have been added.

Applicants note that claims 20-40 were canceled in the original "Request For Filing A Patent Application Under 37 CFR 1.53(b)" filed September 10, 2003 (a copy of which is enclosed with the accompanying Post Card Receipt).

Rejection Under 35 U.S.C. 112

Claims 1-3 and 14-19 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Each of the issues raised by the Examiner are addressed separately hereinbelow.

A. Claim 1, part (iv), has been rejected as indefinite in reciting X_1 and X_2 radicals in the structural formula. The Examiner has questioned if they have different definitions from earlier in the claim. Applicants respectfully disagree.

The terms recited, X_1 and X_2 , are indeed the same as recited in lines 3-5 of the claim. The terms have the same meaning throughout the specification and at no point have they been defined differently. However, in an effort to expedite

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prosecution, the definition recited in lines 3-5 of the claim has been repeated in part (iv).

B. Claim 1, part (iv), has been rejected as indefinite in reciting "said polypeptide group is sufficiently small as to retain the hydrophobicity of said compound introduced by said hydrophobic moiety". The Examiner has indicated that it is not clear what is "said hydrophobic moiety", and that the relative term "sufficiently small" does not set out the metes and bounds of the claim. Applicants respectfully disagree.

Turning first to the recitation of "said hydrophobic moiety", antecedent basis is provided in line 1 of claim 1, part (ii), wherein R_1 is disclosed to be "a hydrophobic moiety". However, in an effort to expedite prosecution, " R_1 " has been inserted before "hydrophobic moiety" in part (iv) of the claim.

With respect to the Examiner's assertion that the phrase "sufficiently small" is indefinite, it is well established that the use of relative terms does not automatically render a claim invalid. For example, a discussion of the factors to be considered when applying 35 U.S.C. 112 to the use of another relative term, "substantially", was provided by the CAFC in *Seattle Box Co. v. Industrial Crating & Packing, Inc.* (CAFC 1984)

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221 USPQ 568. In *Seattle*, the CAFC held that the use of "substantially" was not indefinite, stating that:

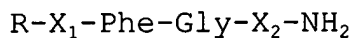
"When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree. The trial court must decide, that is, whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification."

The Court further held that the specification need not set precise limits, and that the claims are patentable under §112 even if some experimentation was required to determine the limits of the claims (page 574). Reaching a similar conclusion, the CCPA held that the use of substantially was not indefinite under §112 in *In re Mattison and Swanson* (CCPA 1975) 184 USPQ 484. As described therein, the CCPA concluded that neither the claims nor the specification need specify numerical limits for what was considered "substantial". Rather, the specification need only set forth general guidelines sufficient to allow a skilled practitioner to make a proper choice of the claimed components:

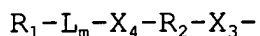
"Hypothesizing whether an increase in efficiency of 3%, 30%, or 300% is necessary for said increase to be classified as substantial is not determinative of the issue of whether the claims satisfy 35 U.S.C. 112, second paragraph."

See also *In re Swinehart and Sfiligoj* (CCPA 1971) 169 USPQ 226, 230, and the more recent *Liquid Dynamics Corp. v. Vaughan Co.* (CAFC 2004) 69 USPQ2d 1595.

Returning to the claim 1 at issue, the claimed invention is drawn to analogs of the insect neuropeptide, allatostatin, wherein a hydrophobic moiety is added to an active portion of the C-terminal allatostatin peptide to render the compound amphiphilic, and thereby enable the compound to penetrate the cuticle of an insect so that it can be topically applied (see the specification at page 5, lines 13-23). The resultant allatostatin analog of the invention is of the formula:



wherein the "R" group includes the hydrophobic moiety. This formula is recited in line 2 of claim 1, and is shown as formula (I) on page 5. Part (b) of claim 1 is drawn to one embodiment of this invention which is described at page 6, line 14, to page 8, line 29. In this embodiment, the R group is of the formula:



wherein R_1 is the hydrophobic moiety, and may be an aromatic amine, aromatic acid, or aliphatic acid. As described in detail in the specification on page 7, lines 7-18, the size of the C-terminal portion of the allatostatin to which the hydrophobic moiety is conjugated may range in size from the C-terminal pentapeptide to a larger C-terminal polypeptide. However, when using a larger polypeptide, if the polypeptide is excessively

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large, the hydrophobic character of the molecule which had been introduced by the R₁ group may be lost, rendering the compound incapable of passing through the insect cuticle. Thus, the specification discloses that when using a larger polypeptide:

"the polypeptide should not be so large as to lose the hydrophobic character introduced by the hydrophobic moiety."

The specification provides further guidelines that the polypeptide should be less than about 20 amino acids, and is preferably equal to about 10 to 12 amino acids.

Thus, the application clearly describes the use of polypeptides larger than five amino acids and provides a thorough description of the limitations on their size. Applicants therefore submit that a practitioner skilled in the art would fully understand what is intended by the claims and the term "sufficiently small", and could readily determine the scope of the claims. It is therefore not necessary to set forth the precise size of the polypeptide.

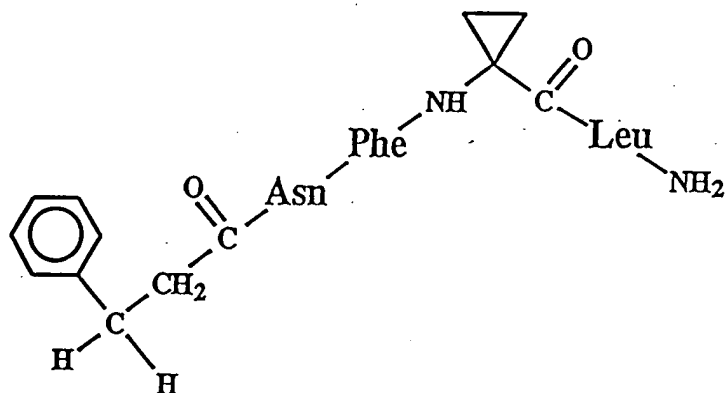
Rejection Under 35 U.S.C. 101, Double Patenting

Claims 1-40 have been provisionally rejected under 35 U.S.C. 101 as claiming the same invention as claims 1-40 of copending application serial no. 10/659,233. Applicants respectfully disagree.

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At the outset, Applicants note that claims 20-40 of the instant application were previously canceled as noted above. Cancellation of those claims has been reaffirmed by this amendment. Similarly, claims 1-40 of the '233 application were canceled by the amendment submitted August 11, 2005, and replaced by claims 41-45. Applicants submit that instant claims 1-20 are clearly distinct from those of the '233 application.

Briefly, claim 41 of the '233 application is limited to a single compound of the formula:



This compound is an analog of the allatostatin neuropeptide which incorporates **two** distinct modifications therein. While the compound contains a first modification to the N terminus of an allatostatin polypeptide to render the compound amphiphilic as described above (in the response to the 35 U.S.C. 112 rejection), the compound also contains a second, additional modification not

claimed in the instant application. This second modification is to substitute a sterically hindered amino acid (in this case Cpa or cyclopropyl alanine) for the second amino acid of the C-terminal allatostatin pentapeptide, as described in the specification at page 9, line 12 to page 12, line 10. The combination of both of the above-mentioned modifications together into the same allatostatin analog is described at page 12, lines 11-26, and page 26, lines 26-34. The resultant compound AST(b)φ2, is shown in Figure 2(c).

In contrast, claims 1-20 of the instant application are not limited to allatostatin analogs having sterically hindered amino acids such as claimed in the '233 application. Indeed, the second amino acid from the C-terminus is glycine or GLY. It is not the cyclopropyl alanine of the '233 application. Thus, the claims of the two applications are not claiming the same invention. Withdrawal of the provisional double patenting rejection is requested.

Rejection Under Obviousness-Type Double Patenting

Claims 1-3, 14 and 15 have been rejected under the doctrine of obviousness-type double patenting as unpatentable over claims 1-7 of U.S. patent 6,664,371.

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In reply, it appears that the Examiner's comments are directed to part (b) of claim 1 wherein the hydrophobic moiety may be aromatic containing amine or acyl groups, or aliphatic fatty acyl groups [see part (b)(ii) of the claim]. It appears that the Examiner's comments are not directed to the compounds of part (a) of claim 1, which is limited to the use of a carborane moiety. Clearly, the claims of patent 6,664,371 do not recite use of a carborane moiety, which is recited in part (a) of instant claim 1.

In view of the current election of species, applicants are unclear as to the Examiner's intent with respect to the compounds of part (b) of instant claim 1. Specifically, it is not clear if the compounds of part (b) have been examined on their merits. This is particularly unclear in view of the Examiner's remarks that dependent claims 4-13 (which are drawn to further limitations of the compounds of part (b) of claim 1) have been withdrawn from further consideration. If it is the Examiner's intent to include the compounds of part (b) in an allowed claim, then applicants here forth agree to submit an executed Terminal Disclaimer under 37 CFR 1.130 and 1.321(c). However, if the Examiner's intent is to cancel part (b) from claim 1 as being drawn to compounds withdrawn from consideration by virtue of

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Applicant's election, then Applicants respectfully submit that a Terminal Disclaimer is unwarranted. If part (b) of claim 1 is cancelled, the instant claims will be limited to compounds containing carboranyl moieties. The use of carboranyl moieties is not disclosed or suggested in the claims of the 6,664,371 patent. Moreover, a practitioner of ordinary skill in the art would have no motivation to substitute such carboranyl moieties for any of the aromatic containing amine or acyl groups or the aliphatic fatty acyl groups of claim 1 of the patent.

Clarification is respectfully requested.

Rejection Under Obviousness-Type Double Patenting

Claims 1-3, 14 and 15 have been rejected under the doctrine of obviousness-type double patenting as unpatentable over claims 1, 3 and 5-17 of U.S. patent 6,207,643. Applicants respectfully disagree.

In reply, the claims of the '643 patent are drawn to allatostatin analogs wherein a sterically hindered amino acid(s) has been substituted for the second and/or third amino acid of the C-terminal allatostatin pentapeptide, and thereby render the compound resistant to degradation by insect peptidase enzymes (see page 9, lines 12-21, and continuing, of the instant

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specification). The claims of the '643 patent do not recite the use of hydrophilic moieties to render the compound amphiphilic as required by the instant claims of record. Moreover, claims 1-20 of the instant application are not limited to the sterically hindered amino acids of the '643 patent claims.

Applicants further note that the instant application is a Continuation of application 09/680,201, which was a Division of the '643 patent. Moreover, the claims of the '643 patent, as filed, were identical to original claims 1-40 in the instant application. The claims in both cases have been subjected to the same restriction requirements imposed by the Examiner. In the '643 patent, Group II, claims 20-33, were elected, while A applicants have elected Group I, claims 1-20, in the instant application.

In view of the restriction requirement imposed by the Examiner, and the fact that the claims in the '643 patent and claims 1-20 in the instant application were in different, patentably distinct groups as identified by the Examiner, applicants respectfully submit that a rejection under the doctrine of obviousness-type double patenting is improper and should be withdrawn. See MPEP 804.01. As set forth therein:

"the third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a

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requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent."

Withdrawal of the rejection is requested.

Rejection Under Obviousness-Type Double Patenting

Claims 1-3, 14 and 15 have been rejected under the doctrine of obviousness-type double patenting as unpatentable over claims 38-40 of copending application 10/385,317, or over claims 1-40 of copending application 10/659,233. Applicants respectfully disagree.

Each of the two applications are addressed separately hereinbelow:

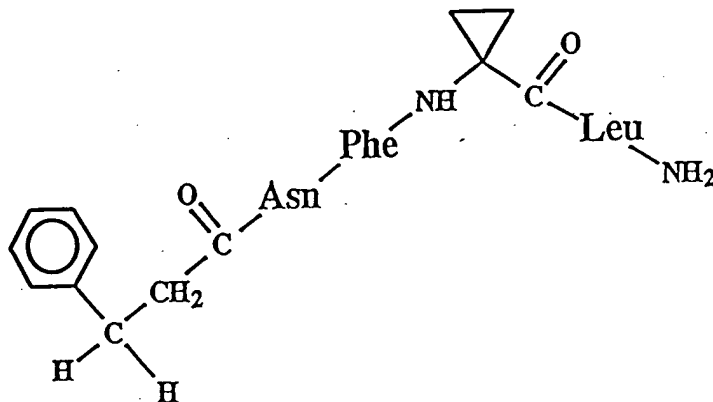
(A) Rejection over claims 38-40 of application 10/385,317

As noted above, the instant application is a Continuation of application 09/680,201, which was a Division of the 6,207,643 patent. Similarly, application 10/385,317 is a Division of the same application 09/680,201. Moreover, as filed, claims 1-40 of the '643 patent, the instant application, and application 10/385,317 were all identical. The claims in all of the applications have been subjected to the same restriction

requirements imposed by the Examiner. In the instant application, Group I, claims 1-19, were elected, while the 10/385,317 application was limited to claims 38-40 (i.e., groups III and VI).

(B) Rejection over claims 1-40 of application 10/659,233

Application 10/659,233 and the claims of record therein were described in the response to the 35 U.S.C. 101 rejection, hereinabove. As noted therein, claim 41 of the 659,233 application is limited to a single compound of the formula:



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Thus, the compound claimed in the 659,233 application is limited to a sterically hindered amino acid (Cpa or cyclopropyl alanine) as the second amino acid of the C-terminal allatostatin pentapeptide (described in the specification at page 9, line 12 to page 12, line 10). In contrast, claims 1-20 of the instant application are not limited to allatostatin analogs having sterically hindered amino acids such as claimed in the '233 application. Indeed, the second amino acid from the C-terminus is glycine or GLY. It is not the cyclopropyl alanine of the '233 application. Applicants respectfully submit that there is no suggestion to replace the sterically hindered Cpa of the '233 application with GLY as claimed in the instant application.

In addition, Applicants again request clarification as to the status of part (b) of instant claim 1. As noted therein, Applicants have elected compounds of part (a) of claim 1, which are all limited to a carborane moiety. However, the claims now of record in the '233 application are not limited to a carborane moiety. There is no suggestion whatsoever of adding a carborane moiety to the compound of claim 41 therein. Applicants respectfully submit that a practitioner of ordinary skill in the art would have no motivation to add a carboranyl moiety to the

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compound of claim 41 of the '233 application. Again, clarification of the status of part (b) of instant claim 1 is requested.

In view of the foregoing, Applicants respectfully submit that claims 1-19 satisfy the requirements of 35 U.S.C. 101 and 112. Allowance thereof is respectfully requested.

Respectfully submitted,



Randall E. Deck, Agent of Record
Registration No. 34,078

Peoria, IL

309/681-6515

FAX: 309/681-6688

Enclosures

1. Copy of Request for Filing a Patent Application
Under 37 CFR 1.53
2. Copy of Correspondence Receipt Post Card